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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,658	11/08/2001	Laurie A. Graham	016252-002110US	6842

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 12/03/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/032,658

Applicant(s)

GU ET AL.

Examiner

Delia M. Ramirez

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-81 is/are pending in the application.
- 4a) Of the above claim(s) 50-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-49 and 78-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 36-81 are pending.

Applicant's election with traverse of Group I, claims 36-49 drawn to the polypeptide of SEQ ID NO: 11 and a liquid composition comprising the polypeptide of SEQ ID NO: 11, in Paper No. 8, filed on 9/30/2002 is acknowledged.

Applicant's traverse is on the ground(s) that all 6 Groups can be examined together without undue burden on the Examiner since the proteins being claimed are not an arbitrary collection of sequences but rather related by virtue of having specific motifs which make them structurally and functionally similar. Applicants also argue that in parent application 08/882907, the prior Examiner examined all the DNA's encoding all the proteins being claimed. Furthermore, Applicants point out that according to the MPEP, the PTO will search at least 10 nucleotide sequences per application unless under exceptional circumstances and that there is no reason to believe that examination of all the proteins in the application would be considered an exceptional case.

Applicant's arguments have been fully considered but are not deemed persuasive to withdraw the restriction requirement. While the Examiner acknowledges Applicant's assertion that the proteins being claimed are related structurally and functionally, a comprehensive search of all the proteins claimed will still require a sequence search of each of the proteins claimed, patented and non-patented literature searches, as well as a class/subclass search. In regard to the examination of application 08/882907 by a previous Examiner, it is noted that restriction is at the discretion of the Examiner. In the instant case, in view of the plurality of independent and

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distinct inventions as well as the burden of search, the Examiner, as stated in previous Office Action Paper No. 6, mailed on 7/26/2002, considered it appropriate to restrict the claims in six Groups.

In regard to the number of sequences that can be examined in a single application, the guidelines set forth in M.P.E.P. § 803.04 clearly indicate that up to (not at least) 10 independent and distinct nucleotide sequences can be examined in a single application. Therefore, the number of sequences to be examined in one single application can vary from 1 to 10. However, in the instant case, searching more than one sequence per application will place an undue burden upon the Examiner and the Office not only because the sequence searches are not co-extensive but also due to the additional computing time required.

The requirement is deemed proper and therefore is made FINAL.

Claims 50-77 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. It is noted that some of the elected claims are still partially drawn to non-elected inventions. Examination of such claims will be restricted to the subject matter elected, which in the instant case is the polypeptide of SEQ ID NO: 11 and composition thereof. Applicants are requested to amend the claims accordingly in response to this Office Action.

Specification

1. The specification is objected to because while the specification contains a reference to a earlier application to which it claims priority to, the status of such earlier application is incorrect. Appropriate correction is required.

Priority

2. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 120 or 121 to US application No. 08/882,907 filed on 6/26/1997.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 11/8/2001 was filed before the mailing date of the first Office Action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

4. The drawings have been reviewed and are objected under 37 CFR 1.84 or 1.152. See attached Notice of Draftsperson's Patent Drawing Review. Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application. In addition, if amendments to the specification are needed due to drawing corrections, Applicant is requested to submit such amendments while the case is being prosecuted to expedite the processing of the application.

Claim Objections

5. Claims 36, 42, 78 are objected to since they are partially drawn to non-elected inventions. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 36-49 and 78-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 36, 41, 78, and 81 (claims 37-40, 42-49, 79-80 dependent thereon) are indefinite in the recitation of “greater than about” or “at least about” because it renders the claims vague and confusing. The use of this language is contradictory because the term “about” can be interpreted as “less than” which is the opposite of “greater than”. Similarly, the term “about” is contradictory because the term “at least” is synonym of “no less than”. It is suggested that the term “about” be deleted. For examination purposes, the term “about” will not be given any patentable weight. Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 36-41, 43-49, 78-81 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptide of SEQ ID NO: 11, does not reasonably provide enablement for any antifreeze protein which has at least 70% sequence identity to the

polypeptide of SEQ ID NO: 11. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2nd 1400 (Fed. Cir. 1988) are: 1) quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

Claims 36-41, 43-49 and 78-81 are directed to antifreeze proteins which are at least 70% sequence identical to the polypeptide of SEQ ID NO: 11, have a molecular weight of 7-13 KDa and a thermal hysteresis activity of more than 1.5 C. The scope of the claims is not commensurate with the enablement provided by the disclosure in regard to the large number of homologs encompassed by the claims. The specification discloses the structure and function of 5 antifreeze proteins and specific motifs however there is no disclosure in the specification of how these specific motifs are related to antifreeze function or the minimum number of these motifs which has to present to display antifreeze function or thermal hysteresis activity of more than 1.5 C. There is no disclosure of which amino acids can be substituted or deleted and still retain antifreeze activity and a thermal hysteresis activity of more than 1.5 C. While one could argue that other antifreeze proteins can be isolated by sequence comparison using the polypeptide structures disclosed in the instant application or the prior art, the state of the art teaches that sequence comparison alone should not be used to determine a protein's function and that small amino acid changes can drastically change the function of a polypeptide. Bork (Genome

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Research, 10:348-400, 2000) teaches protein function is context dependent, and both molecular and cellular aspects must be considered (page 398). Van de Loo et al. (Proc. Natl. Acad. Sci. 92:6743-6747, 1995) teaches that polypeptides of approximately 67% homology to a desaturase from *Arabidopsis* were found to be hydroxylases once tested for activity. Seffernick et al. (J. Bacteriol. 183(8):2405-2410, 2001) teaches that two naturally occurring *Pseudomonas* enzymes having 98% amino acid sequence identity catalyze two different reactions: deamination and dehalogenation, therefore having different function. Broun et al. (Science 282:1315-1317, 1998) teaches that as few as four amino acid substitutions can convert an oleate 12-desaturase into a hydrolase and as few as six amino acid substitutions can transform a hydrolase to a desaturase. The amino acid sequence of the polypeptide determines its structural and functional properties, therefore, one of skill in the art would require some knowledge and guidance as to how structure is related to function in order to isolate polypeptides having antifreeze function and thermal hysteresis activity of more than 1.5 C which are 70% sequence identical to the polypeptide of SEQ ID NO: 11. Therefore, due to the lack of relevant examples, the amount of information provided, the lack of knowledge about the critical structural elements required to display the desired characteristics and function, and the unpredictability of the prior art in regard to function based on homology, one of ordinary skill in the art would have to go through the burden of undue experimentation in order to screen and isolate those polypeptides, as encompassed by the claim, with antifreeze function. Thus, Applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the invention in a manner reasonably correlated with the scope of the claims.

Conclusion


11. No claim is in condition for allowance..
12. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.
13. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
November 25, 2002


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800
1652